

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
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Agenda Item 8

CX/FH 08/40/8
July 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fortieth Session

The Marriot Hotel, Guatemala City, Guatemala

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR *VIBRIO* SPP. IN SEAFOOD AT STEP 3

Prepared by the physical working group led by Japan¹

Governments and interested international organizations are invited to submit comments on the attached Draft Code at Step 3 (see Appendix) and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Seventeenth Edition*) to: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 October 2008.**

Background

1. The 32nd session of the CCFH identified *Vibrio parahaemolyticus* in shellfish as one of the priority issues for consideration by the *ad hoc* Expert Consultation (ALINORM 01/13, para. 18).
2. At the 34th session, CCFH agreed to develop a Discussion Paper on Risk Management Strategies for *Vibrio* spp. in seafood (para. 78, ALINORM 03/13). The Committee further suggested that the initial focus would be *V. parahaemolyticus* in fish and shellfish, as the risk assessments for this bacterium in these products were the most advanced. The Committee agreed that a drafting group led by the United States, with the assistance of Denmark, Japan, Malaysia, Mozambique and Thailand would develop the risk management strategy paper.
3. After the 35th session, the Committee decided to suspend further action on the Discussion Paper until there was dialogue with the Committee on Fish and Fish Products (CCFFP). The paper was therefore not included in the agenda for the 36th session of the Committee. After receiving encouragement from the CCFFP that the CCFH should take the lead, the CCFH agreed that the risk profile would be included on the agenda for the 37th session for further discussion and development.

¹ Australia, Brazil, Canada, European Community, France, Greece, Italy, Mozambique, Norway, Thailand, United States of America, FAO, ICMSF and Codex Secretariat.

4. The CCFFP requested that CCFH continue to work on *Vibrio* spp. risk management with emphasis on bivalve molluscs. In particular, to a) assess the outcome of the Risk Assessments on *Vibrio* spp. in seafood and make recommendations on how this should be transformed into Good Hygienic Practices and risk management strategies and b) address the four areas put forward by the CCFFP related to the risk profile for *Vibrio* spp. (para. 128, ALINORM 4/27/18), specifically, (i) the identification of effective control measures; (ii) the establishment of appropriate microbiological criteria including identification of relevant testing methods; (iii) the need for risk managers to establish tolerances, and (iv) the consideration of source of seafood as a risk factor impacting the control of pathogenic *Vibrio* spp.
5. At the 37th session of the CCFH, the Committee agreed to use the newly established process to consider further work on the Discussion Paper on Risk Management Strategies for *Vibrio* spp. in Seafood, and identified the United States to prepare the written proposal (paras. 167-168, ALINORM 5/28/13).
6. At the 39th session of the CCFH, based on the recommendations of the *ad hoc* Working Group for establishment of CCFH work priorities, the Committee agreed to take up a new work on a Code of Hygienic Practice for *Vibrio* spp. in Seafood (para. 156, ALINORM 08/31/13).
7. Although the codes and standards developed by CCFFP provide information on hygienic practices for fish and fishery products, the level of guidance is not sufficiently detailed in relation to the information needed for a code of hygienic practice that can be used to develop food safety systems based on effective implementation of Good Hygienic Practices and HACCP programs. Accordingly, the purpose of the new work became Fish and Shellfish. It is anticipated that this new work would be undertaken in close collaboration with CCFFP.

Working Group Report

8. The Working Group met in Kyoto, Japan (3-6 June 2008) and developed the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* species in Seafood as instructed by the Committee on Food Hygiene. The Code is presented in Appendix to this document.
9. The Working Group agreed with the overall approach taken in the Proposed Draft Code using the structure of the Recommended International Code of Practice-General Principles of Food Hygiene (CAC/RCP 1-1969). It was stressed that the Proposed Draft Code was intended to apply the recommendations of the Recommended International Code of Practice-General Principles of Food Hygiene to the particular control of pathogenic *Vibrio* spp. in seafood. It was also agreed that this Proposed Draft Code provided guidance on how to achieve the general requirements related to hygiene, in various sections of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).
10. The Working Group agreed that the target microbiological hazards of this Proposed Draft Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleraenic *V. cholerae*. The control measures described in this Proposed Draft Code may be applicable to other pathogenic *Vibrio* spp. which may cause adverse health effects to humans. This Proposed Draft Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state (para.20, the Proposed Draft Code of Hygienic Practice for Pathogenic *Vibrio* spp. in Seafood)
11. The Working Group agreed to introduce definitions for the terms: “refrigeration”, “disinfected seawater”, “clean water”, “artificial seawater” and “seafood”.
12. The Working Group agreed that time and temperature were the most important factors affecting the growth rate of pathogenic *Vibrio* spp. in seafood. In addition, for all seafood, particularly those that are cooked, microbiological cross-contamination is an important issue with respect to pathogenic *Vibrio* spp., especially *V. parahaemolyticus*.

13. The Working Group agreed to recommend the CCFH to develop an Annex to this Proposed Draft Code. The focus of the Annex should be *V. parahaemolyticus* and *V. vulnificus* in molluscan shellfish, as these pathogens/commodity combinations require additional considerations and control measures. This Annex may possibly be expanded to choleraogenic *V. cholerae* as long as there are sufficient data for the additional elaboration of this Annex.
14. The Working Group agreed not to recommend the CCFH develop microbiological criteria for *Vibrio* spp. in reply to the request made by the CCFFP. Based on the risk assessment, it was clear that the risk reduction derived from a certain microbiological criteria was diverse among different parts of the world. Therefore it was difficult to set microbiological criteria, which were applicable worldwide.
15. The 40th Session of the CCFH is invited to consider the attached Proposed Draft Code with a view towards its further progression in the Codex Step Procedure.

APPENDIX

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR PATHOGENIC *VIBRIO* SPECIES IN SEAFOOD AT STEP 3 (N05-2008)

INTRODUCTION

1. During the last several years, there has been an increase in reported outbreaks and cases of foodborne disease attributed to pathogenic *Vibrio* species. As a result, there have been several instances where the presence of pathogenic *Vibrio* spp. in seafood has led to a disruption in international trade. This has been particularly evident with *Vibrio parahaemolyticus* where there has been a series of pandemic outbreaks due to the consumption of seafood, and its emergence has been observed in regions of the world where it was previously unreported. A number of *Vibrio* species are increasingly being recognized as potential human pathogens. The food safety concerns associated with these microorganisms have led to the need for specific guidance on potential risk management strategies for their control.

General Characteristics of Pathogenic Vibrio spp.

2. The genus *Vibrio* contains at least twelve species pathogenic to humans, ten of which can cause food-borne illness. The majority of food-borne illness is caused by *V. parahaemolyticus*, choleraogenic *Vibrio cholerae*, or *Vibrio vulnificus*. *V. parahaemolyticus* and *V. cholerae* are solely or mainly isolated from gastroenteritis cases that are attributable to consumption of contaminated food (both species) or intake of contaminated water (*V. cholerae*). In contrast, *V. vulnificus* is primarily reported from extraintestinal infections (septicaemia, wounds, etc.) and primary septicaemia due to *V. vulnificus* infection is often associated with consumption of seafood.

3. In tropical and temperate regions, these species of *Vibrio* occur naturally in marine, coastal and estuarine (brackish) environments and are most abundant in estuaries. Pathogenic *Vibrio* spp., in particular *V. cholerae*, can also be recovered from freshwater reaches of estuaries, where it can also be introduced by faecal contamination. *V. cholerae*, unlike most other *Vibrio* species, can survive in freshwater environments.

4. It is now possible to differentiate environmental strains of *V. cholerae* and *V. parahaemolyticus* between virulent and avirulent strains based on their ability or inability to produce their major virulence factors. Infection by *V. vulnificus* is characterized by a high fatality rate and is thus considered an important pathogen, but infections are rare and generally limited to individuals with pre-existing chronic illness or who are immunocompromised. The pathogenic mechanisms of *V. vulnificus* have not been clearly elucidated. However, human clinical strains can generally be distinguished from environmental *V. vulnificus* by molecular methods, including rRNA sequence type.

5. The following are important characteristics common to all *Vibrio* spp. *Vibrio* spp. are sensitive to low pH but grow well at high pH, and thus infections caused by *Vibrio* spp. are seldom associated with high-acid foods. In addition, the ingestion of a large number of viable cells is needed for pathogenic *Vibrio* spp. to survive the acidic environment of the stomach and establish an infection. Proper cooking of food products readily inactivates *Vibrio* spp. even in highly contaminated products. Hygienic approaches used with all food-borne pathogens will in general control the growth of pathogenic *Vibrio* spp.

6. There are, however, characteristics specific to each of the three pathogenic species of *Vibrio* that require attention as described below.

Vibrio parahaemolyticus

7. *V. parahaemolyticus* is considered to be part of the autochthonous microflora in the estuarine and coastal environments in the tropical to temperate zones. While *V. parahaemolyticus* typically is undetectable in seawater below 10°C, it can be cultured from sediments throughout the year at temperatures as low as

1°C. *V. parahaemolyticus* is characterized by its rapid growth at favourable conditions. Its multiplication is more rapid in cooked foods rather than raw foods.

8. The vast majority of strains isolated from patients with diarrhea produce a thermostable direct hemolysin (TDH). It has therefore been considered that pathogenic strains possess a *tdh* gene and produce TDH, and non-pathogenic strains lack the gene and the trait. Additionally, it has been suggested that strains that produce a TDH-related hemolysin (TRH) encoded by the *trh* gene should also be regarded as pathogenic. Symptoms of *V. parahaemolyticus* infections include explosive watery diarrhea, nausea, vomiting, abdominal cramps and, less frequently, headache, fever and chills. Most cases are self-limiting, however, severe cases of gastroenteritis requiring hospitalization have been reported. Virulent strains are seldom detected in the environment or in foods, including seafoods, while they are detected as major strains from feces of patients.

9. *V. parahaemolyticus* was first identified as a foodborne pathogen in Japan in the 1950s. By the late 1960s and early 1970s *V. parahaemolyticus* was recognized as a cause of diarrhoeal disease worldwide. A new *V. parahaemolyticus* clone of O3:K6 serotype emerged in Calcutta in 1996. This clone, including its serovariants, has spread throughout Asia and to the USA, elevating the status of the spread of *V. parahaemolyticus* infection to pandemic. In Asia, *V. parahaemolyticus* is a common cause of foodborne disease. In general, the outbreaks are small in scale, involving fewer than 10 cases, but occur frequently. This pandemic *V. parahaemolyticus* has now spread to at least 5 continents. There is a suggestion that ballast discharge may be a major mechanism for global spread of pandemic *V. parahaemolyticus*, but a possibility of export/import seafood-mediated international spread cannot be ruled out.

10. From the point of controlling seafood-borne *V. parahaemolyticus* illnesses, harvest is probably the most critical stage, since it is from this point onwards that individuals can actually implement measures to control *V. parahaemolyticus*.

11. Foods associated with illnesses due to consumption of *V. parahaemolyticus* include crayfish, lobster, shrimp, fish-balls, boiled surf clams, jack-knife clams, fried mackerel, mussel, tuna, seafood salad, raw oysters, clams, steamed/boiled crabmeat, scallops, squid, sea urchin, mysids, and sardines. These products include both raw and undercooked seafood products and cooked products that have been substantially recontaminated through contaminated utensils, hands, etc.

Vibrio cholerae

12. *V. cholerae* is indigenous to fresh and brackish water environments in tropical, subtropical and temperate areas worldwide. Over 200 O serotypes have been established for *V. cholerae*. Strains belonging to O1 and O139 serotypes generally possess the *ctx* gene and produce cholera toxin (CT) and these choleraogenic strains are responsible for epidemic cholera. Epidemic cholera is confined mainly to developing countries with warm climates. Cholera is exclusively a human disease and human feces from infected individuals are the primary source of infection in cholera epidemics. Contamination of food production environments (including aquaculture ponds) by patients' feces can indirectly introduce choleraogenic *V. cholerae* into foods. The concentration of free-living choleraogenic *V. cholerae* in the natural aquatic environment is low, but *V. cholerae* is known to attach and multiply on zooplankton such as copepods.

13. Seven pandemics of cholera have been recorded since 1823. The first six pandemics were caused by the classical biotype strains, whereas the seventh pandemic that started in 1961 and has lasted until now, is due to *V. cholerae* O1 biotype El Tor strains. Epidemic cholera can be introduced from abroad by infected travellers, imported foods and through the ballast water of cargo ships. Detection frequencies of choleraogenic strains of *V. cholerae* from legally imported foods were very low and they have seldom been implicated in cholera outbreaks. *V. cholerae* O139 has been responsible for the outbreaks of cholera in the Bengal area since 1992, and this bacterium has spread to other parts of the world through travellers.

14. Some strains belonging to the O serotypes other than O1 and O139 (referred as non-O1/O139) because food-borne diarrhea that is milder than cholera.

15. Outbreaks of food-borne cholera have been noted quite often in the past 30 years; seafood, including molluscan shellfish, crustaceans, and finfish, are most often incriminated in food-borne cholera cases in many countries. While shrimp has historically been a concern for transmission of cholerae *V. cholerae* in international trade, it has not been linked to outbreaks and it is rarely found in shrimp in international trade.

Vibrio vulnificus

16. *V. vulnificus* can occasionally cause mild gastroenteritis in healthy individuals, but it can cause primary septicaemia in individuals with chronic pre-existing conditions, especially liver disease or alcoholism, following consumption of raw bivalves. This is a serious, often fatal, disease with the highest fatality rate of any known foodborne bacterial pathogen. The ability to acquire iron is considered essential for virulence expression of *V. vulnificus*, but a virulence determinant has not been established and, therefore, it is not clear whether only a particular group of the strains are virulent. The host factor (underlying chronic diseases) appears to be the primary determinant for *V. vulnificus* infection. Incubation period ranges from 7 hours to several days, with the average being 26 hours. The dose response for humans is not known.

17. Of the three biotypes of *V. vulnificus*, biotype 1 is generally considered to be responsible for most seafood-associated human infection and thus the term *V. vulnificus* refers to biotype 1 in this Code.

18. Foodborne illness from *V. vulnificus* is characterized by sporadic cases and an outbreak has never been reported. *V. vulnificus* was isolated from oysters, other molluscan shellfish, and other seafood worldwide.

19. The densities of *V. vulnificus* are high in oysters at harvest when water temperatures exceed 20°C; *V. vulnificus* multiplies rapidly in oysters if not refrigerated. The *V. parahaemolyticus* risk assessment performed in the USA found that water temperature influences levels of this pathogen at harvest and air temperature influences growth rate of this pathogen after harvest.

FAO/WHO Risk Assessments

20. FAO/WHO risk assessments on *V. vulnificus* in raw oysters and cholerae *V. cholerae* O1 and O139 in warm water shrimp in international trade have been published (2005)^{2,3}. Additional risk assessments on *V. parahaemolyticus* in raw oyster, finfish and bloody clams have been completed and are in press^{4,5,6}. These risk assessments constitute the basis of this Code.

Target Hazards and Target Food

21. This Code is based on key findings and outcomes derived from the FAO/WHO microbiological risk assessments. Because of the available risk assessments and recognition as major causative agents of foodborne bacterial illnesses associated with seafood, the target microbiological hazards of this Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and cholerae *V. cholerae*. The control measures described in this Code may be applicable to other pathogenic *Vibrio* spp. which may cause adverse health effects in humans. This Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state.

² FAO and WHO, 2005. Risk assessment of *Vibrio vulnificus* in raw oysters. Microbiological Risk Assessment Series, No.8.

³ FAO and WHO, 2005. Risk assessment of cholerae *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade. Microbiological Risk Assessment Series, No.9.

⁴ FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in raw oysters. Microbiological Risk Assessment Series, No.XX (In press).

⁵ FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in raw and undercooked finfish. Microbiological Risk Assessment Series, No.XX (In press).

⁶ FAO and WHO, 20XX. Risk assessment of *Vibrio parahaemolyticus* in *Anadara granosa* (bloody clams). Microbiological Risk Assessment Series, No.XX (In press).

SECTION I – OBJECTIVES

1.1 THE CODEX GENERAL PRINCIPLES OF FOOD HYGIENE

22. The objective of this Code is to apply the recommendations of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) to the particular case of the control of pathogenic *Vibrio* spp. in seafood. It also provides guidance on how to achieve the general requirements contained in the hygiene sections of the Codex commodity standards for fish and fishery products (*Code of Practice for fish and fishery products* (CAC/RCP 52-2003)). This Code provides guidance on control of pathogenic *Vibrio* spp. in seafood, mainly focusing on seafood to be eaten raw or undercooked, with a view towards protecting the health of consumers and ensuring fair practices in food trade. The primary purpose of this Code is to minimise the likelihood of illness arising from the presence of pathogenic *Vibrio* spp. in seafood. This Code also provides information that will be of interest to the food industry, consumers, and other interested parties.

SECTION II – SCOPE, USE AND DEFINITION

2.1 SCOPE

23. This Code covers seafood, including finfish and shellfish that are marketed in a live, raw, undercooked and cooked state. The target microbiological hazards of this Code are pathogenic *V. parahaemolyticus*, *V. vulnificus* and choleraenic *V. cholerae*.

24. This Code is intended for seafood and is applicable throughout the food chain, from primary production through consumption. Based on the results of the FAO/WHO risk assessment, as well as other available risk assessments and epidemiological evaluations, this Code will focus on control measures that can be used, where appropriate, to minimise and/or prevent the contamination and/or the growth of pathogenic *Vibrio* spp. in seafood. This Code highlights the key control measures that influence the frequency and extent of contamination with pathogenic *Vibrio* spp. and thus the risk of foodborne diseases caused by these pathogens. In many instances, these control measures are articulated in a general manner in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) as part of the general strategy for the control of foodborne pathogens in all foods. In providing this Code, it is assumed that these *General Principles of Food Hygiene* are being implemented. Those principles that are mentioned reflect the need for special attention for the control of pathogenic *Vibrio* spp.

25. Good Hygienic Practices as specified in the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Practice for fish and fishery products* (CAC/RCP 52-2003) and other applicable codes of hygienic practice should be generally suitable to control pathogenic *Vibrio* spp. in cooked seafood. The additional measures described in this Code should be used as necessary to control pathogenic *Vibrio* spp. in raw and undercooked seafood and in ready-to-eat food contaminated with raw seafood.

2.2 USE OF THE DOCUMENT

26. This Code is supplemental to and should be used in conjunction with the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). The application of this Code by countries is likely to require modifications and amendments, taking into account regional differences such as the prevalence of pathogenic *Vibrio* spp. and water temperatures.

2.3 DEFINITIONS

27. For the purpose of this Code, the following definitions apply:

Definitions of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

Refrigeration: The lowering of product temperature to limit microbial activity.

Disinfected seawater: Seawater that received a microbiocidal treatment (*e.g.*, UV irradiation, heat treatment, chlorination) to reduce the number of pathogenic microorganisms including *Vibrio* spp. in seawater so that they do not constitute a health hazard.

Clean water: water that does not contain pathogenic microorganisms at levels that compromise food safety, for example potable water, disinfected seawater, and artificial seawater.

Artificial seawater: a mixture of dissolved mineral salts made with potable water that simulates seawater.

Seafood: Fish, shellfish and other aquatic invertebrates from marine and fresh water sources and their products which are intended for human consumption⁷.

SECTION III - PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE (PRE-HARVEST CONTROL)

28. Refer to Section 3.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). In addition:

29. Generally, pre-harvest controls are more applicable to molluscan shellfish than to other seafood (*e.g.*, open-sea harvested fish). Where relevant to other seafood, pre-harvest controls should be considered for areas where the likelihood of introduction of pathogenic *Vibrio* spp. is significant and can be controlled.

30. Temperature and salinity should be considered for controlling pathogenic *Vibrio* spp. in seafood. Where applicable, specific temperature or salinity levels that can be used as control measures should be identified based on epidemiological and exposure studies as well as monitoring of pre-harvest pathogenic *Vibrio* levels.

31. Monitoring of molluscan shellfish at harvest for the levels of pathogenic *Vibrio* spp. should be conducted to determine the regional and seasonal risk of these microorganisms for the application of appropriate controls.

32. When testing/monitoring parameters go beyond a certain level based on the risk assessment, closing the harvesting area or issuing a public warning, restricting the time to refrigeration, diverting product into cooking or post-harvest processing should be considered.

33. Where predictive models are used to indicate the concentration of pathogenic *Vibrio* spp. in seawater and/or bivalve based on water temperatures and/or salinity, the predictive ability can be improved by incorporating local data and considering additional factors such as hydrodynamic effects (occurrence of tidal waves, rainfall) and sunlight.

34. For seafood grown in coastal locales, especially in cholera-endemic areas, care should be taken to prevent faecal contamination with cholerae *V. cholerae*.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

35. Refer to Section 3.2 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

3.3 HANDLING, STORAGE AND TRANSPORT

36. For the storage and handling of seafood aboard fishing vessels, the use of seawater taken near the seashore or from the region near the mouth of drain or river contaminated with sewage should be avoided. In particular, clean water should be used for seafood intended to be eaten raw, and for preparing ice for such

⁷ For the purposes of this Code, fresh water sources are also included in the definition.

use. Seafood should be held at temperatures that minimise and/or prevent the growth of pathogenic *Vibrio* spp. after harvest, for example, in an ice-water slurry, ice or refrigeration on vessels and at harvest sites.

37. At the landing port, clean water should be used for washing seafood.

38. During on-land transportation from the landing port to the on-shore market and/or processing establishments, in order to minimise and/or prevent the growth of pathogenic *Vibrio* spp. in seafood, the time elapsed between harvest and refrigeration or freezing is critical and should be minimised. Ice can be used efficiently to keep seafood under refrigeration during transportation and selling. In areas where cholerae *V. cholerae* are endemic, enclosed packaging should be used to prevent fecal contamination.

39. For on-boat cooked (boiled, blanched) seafood products, ice and/or refrigeration should be used to facilitate the rapid cooling. Ice made from clean water should be used to minimise cross-contamination.

40. For the storage of live fish, clean water should be used to minimise initial cross-contamination from the water.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

41. Refer to Section 3.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

42. Refer to Section 7.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969). A carrier of cholerae *V. cholerae* should not handle seafood or ice for the storage of seafood, which may result in the contamination of the seafood with cholerae *V. cholerae*.

SECTION IV - ESTABLISHMENT: DESIGN AND FACILITIES

Objectives

43. Equipment and facilities should be designed, constructed and laid out to minimise cross-contamination and recontamination with pathogenic *Vibrio* spp.

4.1 LOCATION

44. Refer to Section 4.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.1.1 Establishments

45. Refer to Section 4.1.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.1.2 Equipment

46. Refer to Section 4.1.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.2 PREMISES AND ROOMS

4.2.1 Design and layout

47. Refer to Section 4.2.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

48. The following practices should be followed, if possible, for live or raw ready-to-eat and cooked ready-to-eat seafood.

49. Whenever feasible, premises and rooms should be designed to separate processing and finished seafood areas. This can be accomplished in a number of ways, including linear product flow (raw materials to finished products) or physical partitions.

50. Where feasible, the washing areas for food equipment involved in the manufacture of the finished product should be located in a separate room from the finished product processing area.

4.2.2 Internal structures and fittings

51. Refer to Section 4.2.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.2.3 Temporary/mobile premises and vending machines

52. Refer to Section 4.2.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.3 EQUIPMENT

4.3.1 General

53. Refer to Section 4.3.1 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.3.2 Food control and monitoring equipment

54. Refer to Section 4.3.2 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

55. The chill room should be equipped with a calibrated thermometer.

4.3.3 Containers for waste and inedible substances

56. Refer to Section 4.3.3 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

4.4 FACILITIES

57. Refer to Section 4.4 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969).

58. Adequate facilities should be provided for the handling and washing of products.

59. Suitable and adequate facilities should be provided for storage and/or production of ice.

4.4.1 Water supply

60. An adequate supply of clean water should be available for handling and washing of seafood to reduce bacterial load of pathogenic *Vibrio* spp. prior to processing.

4.4.2 Drainage and waste disposal

61. All plumbing and waste lines should be capable of coping with peak demands.

62. Accumulation of solid, semi-solid or liquid wastes should be minimised to prevent contamination, because pathogenic *Vibrio* spp. may grow rapidly in these wastes under certain circumstances.

63. Separate and adequate facilities should be provided to prevent contamination by offal and waste material.

4.4.3 Cleaning

64. Refer to Section 4.4.3 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.4 Personnel hygiene facilities and toilets

65. Refer to Section 4.4.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.5.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.5 Temperature control

66. Refer to Section 4.4.5 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 4.1 of *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

67. The *Code of Practice for Fish and Fishery Products* indicates a temperature as close as possible to 0°C. For pathogenic *Vibrio* spp., a temperature of less than 10°C is adequate. The facility should be capable of controlling ambient temperature to ensure that product temperature during processing of raw seafood is maintained at a temperature of $\leq 10^{\circ}\text{C}$.

4.4.6 Air quality and ventilation

68. Refer to Section 4.4.6 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.2 of *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.7 Lighting

69. Refer to Section 4.4.7 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.3 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

4.4.8 Storage

70. Refer to Section 4.4.8 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

SECTION V - CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

71. This section should be applicable from harvest through to food service/catering businesses. Control of pathogenic *Vibrio* spp. will typically require the stringent application of Good Hygienic Practices and other supportive programs. These prerequisite programs, together with HACCP, can provide a sound framework for the control of pathogenic *Vibrio* spp. in seafood.

72. The factors and attributes described below are components of Good Hygienic Practice programs that will typically require increased attention to control pathogenic *Vibrio* spp. and may be used as critical control points in HACCP programs where pathogenic *Vibrio* spp. are identified as a hazard of concern.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Time and temperature control

73. Refer to Section 4.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003). Time and temperature are the most important factors affecting the rate of growth of pathogenic *Vibrio* spp. in seafood.

5.2.2 Specific process steps

5.2.2.1 Washing and processing

74. Clean water should be used for washing and processing seafood at processing establishments.

75. The eviscerated cavity of fish intended for raw consumption (e.g., preparation of sashimi) should be thoroughly washed with clean, preferably running water.

5.2.2.2 Cooking

76. Time and temperature should be determined for each cooking operation to ensure the inactivation of pathogenic *Vibrio* spp.

77. After cooking and blanching, clean water should be used for cooling.

5.2.2.3 Food processing practices

78. Food processing practices (e.g., acidification to pH below 4.8, salting to a sodium chloride concentration of more than 8-10% for *V. parahaemolyticus*, food preservatives (as established by the CCFA), water activity less than 0.94) can be used to minimise the growth and possibly reduce the levels of pathogenic *Vibrio* spp. in seafood.

79. Freezing could be used to reduce the level of pathogenic *Vibrio* spp. in seafood.

80. For pathogenic *V. parahaemolyticus*, several possible inactivation technologies have been reported such as high pressure, mild heating and gamma irradiation. The use of these technologies should be done in accordance with the legislation of the country of retail sale.

81. Any practice selected to control the growth of pathogenic *Vibrio* spp. should be adequately validated to ensure that the process is effective.

82. The food processing practices should be closely monitored and verified to ensure that pathogenic *Vibrio* spp. are controlled as intended.

5.2.2.4 Storage

83. Seafood intended for raw consumption, as well as other ready-to-eat seafood, should be stored in shallow layers and surrounded by sufficient finely divided ice or with a mixture of ice and water before processing.

84. Seafood should be stored so as to avoid over-stacking or over-filling of containers so that cold air can adequately circulate.

5.2.3 Microbiological and other specifications

85. Refer to Section 5.2.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

5.2.4 Microbiological cross-contamination

86. Refer to Section 5.2.4 of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969) and Sections 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

87. For all seafood, particularly those that are cooked, microbiological cross-contamination is an important issue with respect to pathogenic *Vibrio* spp., especially *V. parahaemolyticus*. It can occur through direct contact with raw fish, personnel, aerosols and contaminated utensils, equipment, etc. Cross-contamination can occur at any step where the food is exposed to the environment, including processing, transportation, retail, catering, in restaurants, and in the home through contact with contaminated raw seafood directly, or indirectly through water, chopping boards, etc.

5.2.5 Physical and chemical contamination

88. Refer to Section 5.2.5 the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.2.2 and 3.3.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.3 INCOMING MATERIAL REQUIREMENTS

89. Refer to Section 5.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 8.5.1 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.4 PACKAGING

90. Refer to Section 5.4 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 8.5.2 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

5.5 Water

5.5.1 In contact with food

91. Refer to Section 5.5.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) except cases specified within this Code where clean water could be used.

92. Coastal seawaters used at landing docks and at markets have been shown to be occasionally contaminated with high level of pathogenic *V. parahaemolyticus*. Therefore, the post-harvest stage may be of particular importance for preventing seafood from becoming contaminated with pathogenic *Vibrio* spp.

5.5.2 As an ingredient

93. Refer to Section 5.5.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.5.3 Ice and steam

94. Refer to Section 5.5.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.6 MANAGEMENT AND SUPERVISION

95. Refer to Section 5.6 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.7 DOCUMENTATION AND RECORDS

96. Refer to Section 5.7 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

5.8 RECALL PROCEDURES

97. Refer to Section 5.8 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

SECTION VI - ESTABLISHMENT: MAINTENANCE AND SANITATION

98. Refer to Section 6 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.4 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

SECTION VII - ESTABLISHMENT: PERSONAL HYGIENE

99. Refer to Section 7 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.5 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

SECTION VIII – TRANSPORTATION

100. Refer to Section 8 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Sections 3.6 and 17 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

101. Transportation is an integral step in the food chain and temperature during this period should be controlled, monitored and recorded where appropriate.

SECTION IX - PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 LOT IDENTIFICATION

102. Refer to Section 9.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.2 PRODUCT INFORMATION

103. Refer to Section 9.2 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

9.3 LABELLING

104. Refer to the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985). Where appropriate, product labels should include information on safe handling practices and storage recommendations.

105. Countries should give consideration to labelling of certain live and raw seafood, so that consumers can make informed choices with respect to the safety and true nature of these products. In particular, any physical or chemical treatment (*e.g.*, heat treatment, high-pressure, irradiation), applied to the product, in addition to normal processing, should be mentioned on the label.

9.4 CONSUMER EDUCATION

106. Since each country has specific consumption habits, communication and education programs pertaining to pathogenic *Vibrio* spp. are most effective when established by individual governments.

107. Programs should be directed at consumers:

- to educate them on household practices and behaviours that would specifically keep the numbers of pathogenic *Vibrio* spp. that may be present in foods, to as low a level as possible and minimise the potential of cross-contamination from seafood to hands of food handlers, and then from hands to other foods, or from seafood to utensils (e.g., cutting board), and then from utensils to other foods by:
 - keeping seafood cold to minimise and/or prevent the growth of pathogenic *Vibrio* spp.;
 - keeping refrigerator temperatures as low as practical;
 - using thermometers inside home refrigerators, ice chests or other storage containers;
 - preparing, cooking and/or consuming seafood immediately after removing them from the refrigerator;
 - promptly refrigerating leftover seafood;
 - washing and disinfecting hands, utensils and equipments whenever raw seafood is handled; and
 - separating utensils and equipment used for raw seafood, from other ready-to-eat foods, where appropriate.
- to help them make informed choices about the purchase, storage, shelf-life labelling and appropriate consumption of certain raw seafoods that have been identified in relevant risk assessment and other studies, taking into consideration the specific regional conditions and consumption habits.

9.4.1 Special Attention to Susceptible Subpopulations

108. Liver disease is a prominent risk factor for human infection with pathogenic *Vibrio* spp., especially *V. vulnificus*. Additional risk factors can be observed in the *V. vulnificus* and *V. parahaemolyticus* risk assessments.⁸ Subpopulations with increased susceptibility should follow the advice below:

- avoid the consumption of raw or undercooked seafood; and
- heat seafood thoroughly.

SECTION X - TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

109. Refer to Section 10.1 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

110. Industry (fishermen, primary producers, manufacturers, distributors, retailers and food service/institutional establishments) and trade associations play an important role in providing specific instructions and training for the control of pathogenic *Vibrio* spp.

10.2 TRAINING PROGRAMMES

111. Personnel involved in the harvesting, processing and handling of seafood should have appropriate training for the tasks they are performing. This may include:

⁸ FAO and WHO, 2005. Risk assessment of *Vibrio vulnificus* in raw oysters. Microbiological Risk Assessment Series, No.8.

- the nature of pathogenic *Vibrio* spp., namely *V. parahaemolyticus*, choleraenic *V. cholerae* and *V. vulnificus*, their harbourage sites, and their resistance to various environmental conditions to be able to conduct a suitable hazard analysis for their products;
- control measures for reducing the risk of pathogenic *Vibrio* spp. associated with seafood during harvesting, processing, distribution, marketing, use and storage, for preventing cross-contamination and minimizing the growth of pathogenic *Vibrio* spp.; and
- the means for verifying effectiveness of control programs, including sampling and analytical techniques.

10.3 INSTRUCTION AND SUPERVISION

112. Refer to Section 10.3 of the *Recommended International Code of Practice- General Principles of Food Hygiene* (CAC/RCP 1-1969).

10.4 REFRESHER TRAINING

113. Refer to Section 10.4 of the *Recommended International Code of Practice-General Principles of Food Hygiene* (CAC/RCP 1-1969) and Section 3.8 of the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).